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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/839,778	04/20/2001	James N. Herron	3278.1US	3373

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EXAMINER
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LAM, ANN Y

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 06/30/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Applicati n N .

09/839,778

Applicant(s)

HERRON ET AL.

Examiner

Ann Y. Lam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 22-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2. 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of the restriction requirement in Paper No. 4 is acknowledged. The traversal is on the ground(s) that independent claim 1, like independent claim 22, does not recite use of a waveguide, and thus, is not limited to use of a waveguide. This is not found persuasive because claim 1 and 22 are related as combination and subcombination. The subcombination requires use of specific reactive elements and the subcombination has separate utility such as for use in protein binding kinetic studies. Thus, the inventions are distinct.

The requirement is still deemed proper and is therefore made FINAL.

### ***Information Disclosure Statement***

The information disclosure statement filed April 20, 2001 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. (Copies of the foreign patent documents and "other documents" listed were not found by Examiner.)

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites the limitation "the detection" in line 1. There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Jackowski, 5,747,274. Jackowski discloses a method evaluating the presence of a plurality of analytes in a sample, at least one analyte having known parameters indicative of an acute metabolic or disease state, see column 4, lines 32 - column 8, line 31, and column 19, lines 8-14; substantially simultaneously determining concentrations of each of the analytes; continuing the determination until the analyte has been reliably determined to be present in an amount indicative of the metabolic or disease state, see

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column 29, lines 51-63; and reporting said determination in an amount indicative of the metabolic or disease state, see column 29, lines 51-63.

As to claim 2, the detection of at least one other analyte continues after the report in order to accurately determine the presence or concentration of the analyte, see column 22, lines 1-12.

As to claim 3, the method further comprises evaluating binding of the analytes to corresponding reactive elements over a plurality of time points, see column 22, lines 6-12.

As to claim 4, the determination is effected by reacting at least one analyte with a corresponding reactive element, see column 19 lines 15-22.

As to claim 5, the determination includes exposing the sample to the reactive elements, see column 11, lines 1-12.

As to claim 6, each reactive element is immobilized on a waveguide surface, see column 27, lines 38-58, and column 29, lines 1-27.

As to claims 7 and 12, the continuation includes correlating a rate of reaction between the analyte and the reactive element to a concentration of the analyte, see column 2, lines 53-59, see column 29, lines 50-55, and column 32, lines 19-31.

As to claim 8, the reactive elements are arranged in a pattern on the waveguide surface, see column 27, lines 38-58, and column 29, lines 1-27.

As to claim 9, the determination includes introducing a light beam including at least one wavelength for stimulating a light signal from the reactive element when the

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reactive element has coupled with the analyte, see column 27, lines 38-58, and column 29, lines 1-27.

As to claim 10, the light signal is indicative of a rate of reaction between the analyte of interest and the reactive element, see column 27, lines 37 column 28, line 11.

As to claim 11, the determination includes measuring the light signal generated from the reaction of the analyte with the reactive element, see column 27, lines 37 column 28, line 11.

As to claim 13, the analyte is a marker released from cardiac tissue only after a myocardial infarction, see column 1, lines 63-67.

As to claim 14, the marker comprises myoglobin, see column 4, line 36=5.

As to claim 15, the analyte is a cardiac specific marker, see column 1, lines 63-67.

As to claims 16-19, the analyte comprises troponin as claimed, see column 7, lines 34-37.

As to claim 20, the analyte comprises creatine kinase, see column 5, lines 29-31.

As to claim 21, the creatine kinase comprises CK-MB, see column 5, lines 29-31.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Shah et al., 4,900,662, discloses method and reagents for early detection of myocardial infarction. Erb et al., 6,300,082, discloses use of a waveguide for measuring binding between molecules.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is (703) 306-5560. The examiner can normally be reached on M-TH 8-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703)305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-4242 for regular communications and (703)308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

A.L.

June 27, 2003



LONG V. LE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

06/24/03